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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

LEFFERS JR, G

ART UNIT	PAPER NUMBER
1636	5

DATE MAILED:

05/19/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**Office Action Summary**

Application No.

09/404,448

Applicant(s)

Byrne, et al.

Examiner

Gerald G. Leffers Jr.

Group Art Unit

1636

 Responsive to communication(s) filed on \_\_\_\_\_. This action is **FINAL**. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims** Claim(s) 1-41 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

 Claim(s) \_\_\_\_\_ is/are allowed. Claim(s) \_\_\_\_\_ is/are rejected. Claim(s) \_\_\_\_\_ is/are objected to. Claims 1-41 are subject to restriction or election requirement.**Application Papers** See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948. The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner. The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved. The specification is objected to by the Examiner. The oath or declaration is objected to by the Examiner.**Priority under 35 U.S.C. § 119** Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d). All  Some\*  None of the CERTIFIED copies of the priority documents have been received. received in Application No. (Series Code/Serial Number) \_\_\_\_\_. received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

 Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).**Attachment(s)** Notice of References Cited, PTO-892 Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_ Interview Summary, PTO-413 Notice of Draftsperson's Patent Drawing Review, PTO-948 Notice of Informal Patent Application, PTO-152**--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---**

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## **DETAILED ACTION**

### ***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-28, drawn to a DNA segment comprising an AAVrep coding sequence, an AAV cap coding sequence, HSV origin of replication and packaging sequence, and to an HSV-1 helper virus, classified in class 435, subclass 320.1; class 536, subclass 23.1.
  - II. Claims 29-34 and 36-40, drawn to methods of making rAAV virus, classified in class 424, subclass 93.2; class 435, subclass 325.
  - III. Claims 35 and 41, drawn to kits comprising rAAV virus, classified in class 424, subclass 93.2; class 435, subclass 320.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Group I and Group II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products of Group I could be used as a source for AAV rep and cap sequences for subsequent cloning into different vectors.

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The DNA segments and vectors of Group I are chemically, biologically, structurally and functionally distinct from the rAAV viruses of Group III. The DNA segments and vectors of Group I are not required to make the rAAV viruses of Group III (which can be made with packaging cells comprising cap and rep expressed from other sources) and the rAAV viruses of Group III are not required for the production of the DNA segments and vectors of Group I (which can be replicated in or as vectors). Therefore, the inventions of the two groups are capable of supporting separate patents.

Inventions of Group II and Group III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the rAAV viruses of Group III can be made in packaging cells comprising rep and cap genes expressed from a different source than the DNA segments and vectors of Group I.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

A telephone call was made to Barbara Kitchel on or about 3/21/00 to request an oral election to the above restriction requirement, but did not result in an election being made.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Conclusion***

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald Leffers, Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about

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5:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than 24 hours after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. George Elliott, can be reached on (703) 308-4003.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*AG2*  
G. Leffers, Jr.

Patent Examiner

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May 16, 2000

*Terry A. McKelvey*

TERRY MCKELVEY  
PRIMARY EXAMINER